Valved Balloon Stent

<u>Cross-reference to Related Applications</u>

This is the national stage of International Application ser. no. PCT/EG2003/000010, filed Nov. 23, 2003, and claiming the benefit of Egyptian application no. 2003090946, filed Sep. 24, 2003.

Background

Previous state of the art:

A surgical procedure is undertaken with its inherent costs, risks and problems to replace the non functioning valve with another human, animal or metallic.

Fixing an animal origin valve through catheterization.

Problems in the previous state of the art:

High cost and associated risks of surgical operation for valve replacement.

Non malleability in dealing with the valve after its placement.

The high cost of the valve itself.

Brief Description of the Drawing

FIG. 1 demonstrates a sketch of the invention.

Detailed Description

This invention is concerned with a lined inflatable and dilatable valved balloon stent (the stent is dilatable and its lining is either inflatable or dilatable, the balloon is inflatable and deflatable) that will be introduced inside vessels to function as a valve.

So that the stent is introduced in its smaller size then dilated to take the size of the intended vessel; the balloon will then be inflated with an appropriate material e. g. carbon dioxide, normal saline, air.

Apart from the central balloon the proximal opening can be inflatable.

In simpler terms, it's a cage like design mounted on the dilatable stent having a narrower opening on one side and the cage from the other side (the narrowing can be inflatable) and an inflatable ball enclosed. This ball functions as the valve.

For this purpose the metallic dilatable stents in common use in cardiology practice can be modified to this new shape. The balloon moving inside the cage can be prepared from any inflatable and non reactive tissue e.g. similar to valvotomy balloons in common practice.

As shown in **FIG. 1**, ball valve **10** for controlling flow of fluids or gases may include dilatable stent **12** having a proximal end **14** and a distal end **16**; cage-shaped barrier **18** covering the proximal end of the stent; orifice **20** at the distal end of the stent, the orifice having a size b; inflatable ball **22** having a size a larger than the orifice size; and inflatable lining **24** that lines the stent and defines the size of the orifice. The ball is trapped in the stent by the cage-shaped barrier and the orifice. The ball is free to move inside the stent. Contact of the ball against the inflatable lining blocks fluid or gas flow through the distal end of the stent.

During placement of this valved balloon stent, the previous damaged non functioning valve can be crushed (putting the new valve in the place of the old one exactly).

This procedure will be done through per catheter intervention in the catheterization laboratory. It will allow emergency as well as permanent valve replacement when other options are worrisome.

I expect it thus to revolutionize the practice. Because the ability to perform per catheter inflatable valve replacement without mortality will definitely make surgical corrections of simple as well complicated cardiac lesions be not needed or at least deferrable to the time where they could be done with less mortality.

What is new about this invention?

Achieve the same result of surgery through interventional catheterization.

Malleability in the dealing with the valve during and after placement.

Avoiding the risks and costs of the surgical or operation.

Examples

- 1. The addition of inflatable and/or compressible and/or controllable lining to stents (medical or non medical) to function as a valve for the flow of fluids or gases through. a. This includes any form of stents including but not limited to metallic, plastic, totally inflatable stents or otherwise of medical or non medical use. b. This includes all shapes of stent designs including but not limited to ring, tubular, cylindrical, cone, pentagonal... etc. c. This includes all shapes and materials of linings used for the same purpose including but not limited to ePTFE and PTFE.
- 2. The addition of fixed lining narrowing excluding animal native or treated valves to stents (medical or non medical) to function as a valve for the flow of fluids or gases through. a. This includes any form of stents including but not limited to metallic, plastic, totally inflatable stents or otherwise of medical or non medical use. b. This includes all shapes of stent designs including but not limited to ring, tubular, cylindrical, cone, pentagonal... etc. c. This includes all shapes and materials of linings used for the same purpose including but not limited to ePTFE and PTFE.
- 3. Stentless designs used for the same purpose (to function as a valve for the flow of fluids or gases through a vessel). The implantation techniques includes but is not limited to interventional, surgical or endoscopic).
- 4. The use of this technique includes but is not limited to inside the blood vessels, airways, urinary, gastrointestinal passages or industrial pipes.

Ser. No. 10/572,737 Substitute Specification

This includes but is not limited to the design suggested above for this purpose.

6. The designs that will achieve the valve function for the flow inside the vessel in one or more than one direction are included as well.